

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

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M.B.

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/465,338 12/17/99 ALBERT

K PT-1817

HM12/0503

EXAMINER

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AIR MAIL

ART UNIT PAPER NUMBER

1615

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DATE MAILED:

05/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/465,338	ALBERT ET AL.
Examiner	Art Unit	
Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) Responsive to communication(s) filed on 12/17/99.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-62 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-62 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims 1-62 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 17 December 1999 is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - a) All b) Some * c) None of the CERTIFIED copies of the priority documents have been:
 1. received.
 2. received in Application No. (Series Code / Serial Number) _____.
 3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) <input type="checkbox"/> Notice of References Cited (PTO-892)	17) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
15) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	18) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
16) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2	19) <input type="checkbox"/> Other: _____

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DETAILED ACTION

Receipt is acknowledged of the Information Disclosure Statement, Petition to Make Special, and the Preliminary Amendment A, received March 29, 2000, March 29, 2000, and March 31, 2000, respectively.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Drawings

The drawings are objected to because of the reasons specified on the attached PTO 948. Correction is required.

Claim Objections

Claims 4-18, 22-55, 61, and 62 are objected to under 37 CFR 1.75(c) as being in improper form for one of two reasons: The claim is a multiple dependant claim, which improperly depends on another multiple dependant claim, or the claim is a dependant

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claim, which depends on an improper multiple dependant claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 13, 14, 16, 45, 48, 50, 52, 56, 59, and 60 are rejected under 35 U.S.C. 112, second paragraph, because they contain one of the following trademark/trade names: Eudragit NE30 D, or Avicel, or Eudragit RS, or Eudragit RL. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe specific chemical compounds and, accordingly, the identification/description is indefinite.

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Claims 1, 2, and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "540 mg or more" is considered vague, as it does not define a specific amount of the active ingredient. Correction is required.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 is written in a manner which is difficult to interpret. It is suggested that the claim be rewritten as follows:

Preparation of claim 1 wherein the preparation comprises microgranules, wherein each microgranule comprises a central core of diltiazem or a pharmaceutically acceptable salt thereof, associated with a wetting agent, wherein the central core is coated with a microporous membrane.

Claims 11, 15, and 45 are rejected under 35 U.S.C. 112, second paragraph for lack of antecedent basis in a claim. These claims recite the limitation "bead" in claims 9, 14 and 9, respectively. There is insufficient antecedent basis for this limitation in the claims.

Claims 12, 13, 18, 44, 45, 50, 52, 56, and 59, are rejected under 35 U.S.C. 112, second paragraph based on the phrase "such as" which renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

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Claim 18 is also rejected under 35 U.S.C. 112, second paragraph, based on the phrase "or the like" which renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim 18 is also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "higher pH regions" is considered vague and appropriate correction is required.

Claim 44 is rejected under 35 U.S.C. 112, second paragraph. The language in this claim is confusing because it is an improperly worded Markush claim. Section 2173.05 (h), part I of the MPEP states that a Markush group recites members as being "selected from the group consisting of A, B, and C." *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925). The MPEP further states that it is improper to use the term "comprising" instead of "consisting of." *Ex parte Dotter*, 12 USPQ 382 (Bd. App. 1931).

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to

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whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 44 recites the broad recitation "C₁₂ to C₂₀ fatty acid esters of saccarose," and the claim also recites "commercialized under the name of sucroesters (Gattefosse, France), or under the name of crodester (Croda, U.K.) such as sucrose stearate marketed under the trade name of Crodesta" which is the narrower statement of the range/limitation. The claim then recites the broad recitation "esters of fatty acids and polyoxyethylene," and the claim also recites "(Brijs, Renex, and Eumulgines, Henkel, RFA)," which is the narrower statement of the limitation. The claim then recites the broad recitation "sorbitan fatty acid esters," and the claim also recites "(Span, Atlas, U.S.A.)," which is the narrower statement of the limitation. The claim then recites the broad recitation "polyglycides-alcohol ester," and the claim also recites "Gelucires, Gattefosse, France," which is the narrower statement of the limitation. All of the narrower statements of the limitations need to be deleted from the claim.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-36 are rejected under 35 U.S.C. 102(b) as being anticipated by EPA 856 313 to Geoghegan *et al.* ('313).

EPA '313 discloses a controlled absorption diltiazem pellet formulation for oral administration to control hypertension and angina comprising a core of diltiazem or a pharmaceutically acceptable salt thereof, and a multilayer membrane surrounding the core and containing both a water insoluble and a water soluble polymer (abstract). EPA '313 further discloses that the formulation is preferred as a once-daily product to be administered before bedtime, and to be released at the following rates:

- a. from 0 to 35% after 2 hours
- b. from 4 to 45% after 4 hours
- c. from 30 to 75% after 8 hours
- d. from 60 to 95% after 13 hours
- e. not less than 85% after 24 hours.

These release rates overlap those claimed by applicant in the instant application.

Further, EPA '313 teaches that the water insoluble polymer can be replaced by a copolymer of acrylic and methacrylic acid esters (p 28, claim 10), and that the water

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soluble polymer can be HPMC (p 28, claim 7). EPA '313 also teaches that the core may comprise an organic acid, a lubricant (p 5, l 15-29), and other pharmaceutically acceptable components. Although EPA '313 does not disclose the exact release rates claimed by applicant, the ranges claimed fall within the range disclosed by EPA '313, and therefore are anticipated by the reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-47, 49-59, 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over EPA 856 313 to Geoghegan et al. ('313) as applied to claims 1-36 above.

EPA '313 does not teach the specific amounts of Diltiazem present in the formulation, nor do they teach the specific wetting agent claimed by applicant. However, the formulation disclosed in EPA '313 does acknowledge the presence of additional additives, such as lubricants. Further, the formulation also releases the drug at the same rate as that claimed by applicant, therefore, it appears that these limitations do not render any unexpected results. It is the position of the examiner that these are

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limitations which would be routinely determined by one of ordinary skill through minimal experimentation, as being suitable, absent the presentation of some unusual and/ or unexpected results. The results must be based on the specific limitations.

Claims 1-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/00093 to Deboeck *et al.* ('093). WO '093 discloses an extended release galenical form of Diltiazem or a pharmaceutically acceptable salt, with a wetting agent, coated with a microporous membrane comprising at least a water soluble polymer and a pharmaceutically acceptable adjuvant. WO '093 further teaches that the composition comprises beads containing between 120 and 480 mg of the active ingredient, with the wetting agent, and the beads are coated with the microporous membrane (p 19, claim 1). WO '093 further teaches that the water soluble polymer or copolymer can include HPMC and Eudragit (p 8, I 21-28). Further, WO '093 teaches that the following ingredients are included in the formulation: wetting agents such as fatty acid esters of saccharose (2-20%), microcrystalline cellulose (5-25%), polyvinylpyrrolidone (1-15%), titanium oxide, surfactants such as tween, antifoaming agents, magnesium stearate, and talc (see pages 8-10). These are the ingredients disclosed by applicant as being present in the formulation. WO '093 also teaches that the formulation is for once daily administration. WO '093 does not teach the exact rates of release as claimed by applicant, nor do they discuss the rates of release after 8 hours, nor do they disclose all of the specific amounts of the above mentioned ingredients. However, WO '093 does

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teach overlapping rates of release to those claimed by applicant, and they do teach the same ingredients as claimed by applicant. It is the position of the examiner that the present application is not patentably distinct from WO '093, as they contain the same ingredients, in the same formulation, with overlapping rates of release, even though WO '093 does not disclose the specific amounts of all the ingredients. It is the position of the examiner that the specific amounts of those ingredients which are not disclosed in WO '093 are limitations which would be routinely determined by one of ordinary skill in the art through minimal experimentation, absent the presentation of some unusual and/or unexpected results. The results must be those that accrue from the specific limitations. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to create a controlled release formulation of Diltiazem, based on the teachings of WO '093, and experiment with and vary the specific amounts of the ingredients, in order to achieve the desired rate of release.

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention: tablet form and capsule form.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 56, and 59 are generic.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy Pulliam, whose telephone number is (703) 308-4710. The examiner can normally be reached Monday to Friday from 7:30 am to 4:00 pm.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703) 308-1234.

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